K093268

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MAY 11 2010

510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 C.F.R. §807.92.

1. The submitter of this premarket notification is:

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This summary was prepared on May 10, 2010.

2. The names of the devices are the Philips MP2, X2, MP5, MP20, MP30, MP40, MP50, MP60, MP70, MP80, and MP90 IntelliVue Patient Monitors
Classification names are as follows:

Device Panel	Classification	ProCode	Description
Cardiovascular Devices	§870.1025, II	DSI	Detector and alarm, arrhythmia
	§870.1025, II	MLD	Monitor, ST Segment with Alarm
	§870.1025, II	MHX	Monitor, Physiological, Patient (with arrhythmia detection or alarms)
	§870.1100, II	DSJ	Alarm, Blood Pressure
	§870.1110, II	DSK	Computer, Blood Pressure
	§870.1130, II	DXN	System, Measurement, Blood-Pressure, Non-Invasive
	§870.1435, II	DXG	Computer, Diagnostic, Pre-Programmed, Single-Function
	§870.1915, II	KRB	Probe, Thermodilution
	§870.2060, II	DRQ	Amplifier and Signal Conditioner, Transducer Signal
	§870.2300, II	DRT	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm)
	§870.2340, II	DPS	Electrocardiograph
	§870.2340, II	MLC	Monitor, ST Segment
	§870.2350, II	DRW	Electrocardiograph, Lead Switching Adapter
	§870.2370, II	KRC	Tester, Electrode, Surface, Electrocardiograph
	§870.2600, I	DRJ	System, Signal Isolation
	§870.2700, II	DQA	Oximeter
	§870.2770, II	DSB	Plethysmograph, Impedance
	§870.2800, II	DSH	Recorder, Magnetic tape, Medical
	§870.2810, I	DSF	Recorder, Paper Chart
	§870.2850, II	DRS	Extravascular Blood Pressure Transducer
	§870.2900, I	DSA	Cable, Transducer and Electrode, incl. Patient Connector
	-	MSX	System, Network and Communication, Physiological Monitors

Device Panel	Classification	ProCode	Description
	§870.2910, II	DRG	Transmitters and Receivers, Physiological Signal, Radiofrequency
Anesthesiology Devices	§868.1400, II	CCK	Analyzer, Gas, Carbon Dioxide, Gaseous-Phase
	§868.1500, II	CBQ	Analyzer, Gas, Enflurane, Gaseous-Phase (Anesthetic Concentration)
	§868.1500, II	NHO	Analyzer, Gas, Desflurane, Gaseous-Phase (Anesthetic Concentration)
	§868.1500, II	NHP	Analyzer, Gas, Sevoflurane, Gaseous-Phase (Anesthetic Concentration)
	§868.1500, II	NHQ	Analyzer, Gas, Isoflurane, Gaseous-Phase (Anesthetic Concentration)
	§868.1620, II	CBS	Analyzer, Gas, Halothane, Gaseous-Phase (Anesthetic Concentration)
	§868.1700, II	CBR	Analyzer, Gas, Nitrous Oxide, Gaseous-Phase (Anesthetic Concentration)
	§868.1720, II	CCL	Analyzer, Gas, Oxygen, Gaseous-Phase
	§868.1880, II	BZC	Data calculator Pulmonary-function
	§868.2375, II	BZQ	Monitor, Breathing Frequency
	§868.2480, II	LKD	Monitor, Carbon Dioxide, Cutaneous
	§868.2500, II	KLK	Monitor, Oxygen, Cutaneous, for Infant not under Gas Anesthesia
General Hospital and Personal Use Devices	§880.2910, II	FLL	Thermometer, Electronic, Clinical
Neurological Devices	§882.1400, II	GWR	Electroencephalograph
	§882.1420, I	GWS	Analyzer, Spectrum, Electroencephalogram Signal

3. The modified devices are substantially equivalent to previously cleared Philips IntelliVue Patient Monitors marketed pursuant to K021778, K030038, K032858, K033444, K033513, K040304, K040357, K041235, K042845, K050762, K051106, K052801, K053522, K060221, K060541, K061052, K061610, K062283, K063315, K062392, K063725, K71426, K72020.

4. The modification is the introduction of software release G.08 for the entire IntelliVue Patient Monitors family, models MP2, X2, MP5, MP20, MP30, MP40, MP50, MP60, MP70, MP80, and MP90 including enhancements in the Respiration algorithm.

5. The modified devices have the same intended use as the legally marketed predicate devices. The Philips MP2, X2, MP5, MP20, MP30, MP40, MP50, MP60, MP70, MP80, and MP90 IntelliVue Patient Monitors are intended for monitoring and recording of and to generate alarms for, multiple physiological parameters of adults, pediatrics and neonates in hospital environments. The MP2, X2, MP5, MP20, MP30, MP40, and MP50 are additionally intended for use in transport situations within hospital environments. The MP5 is also intended for use during patient transport outside of a hospital environment. The monitors are not intended for home use. They are intended for use by health care professionals.

6. The modified devices have the same technological characteristics as the legally marketed predicate device.

7. Verification, validation, and testing activities establish the performance, functionality, and reliability characteristics of the modified devices with respect to the predicate. Testing involved system level and regression tests as well as testing from the hazard analysis. Pass/Fail criteria were based on the specifications cleared for the predicate devices and test results showed substantial equivalence. The results demonstrate that the Philips IntelliVue Patient Monitors meet all reliability requirements and performance claims.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Philips Medizin Systeme Boeblingen GmbH
c/o Mr. Andreas Suchi
Senior Regulatory Affairs Engineer
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Germany

MAY 11 2010

Re: K093268
Trade/Device Name: Philips Intellivue Patient Monitor Models MP2, X2, MP5, MP20, MP30, MP40, MP50, MP60, MP70, MP80 and MP90
Regulatory Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm (Including ST-Segment Measurement and Alarm)
Regulatory Class: Class II (Two)
Product Code: MHX
Dated: May 4, 2010
Received: May 5, 2010

Dear Mr. Suchi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K093268

Device Name: Philips MP2, X2, MP5, MP20, MP30, MP40, MP50, MP60, MP70, MP80, and MP90 IntelliVue Patient Monitors, Software Revision G.08.

Indications for Use: Indicated for use by health care professionals whenever there is a need for monitoring the physiological parameters of patients.

Prescription Use (Part 21 CFR 801 Subpart D)	___yes__	AND/OR	Over-The-Counter Use (21 CFR 807 Subpart C)	__No___

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number 3/11/10